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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

PLAINTIFFS' RESPONSE IN OPPOSITION TO BARD'S MOTION FOR PROTECTIVE ORDER

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I. INTRODUCTION

Plaintiffs oppose the Defendants' Motion and Incorporated Memorandum for a Protective Order Regarding Report of Dr. John Lehmann ("Motion").

The December 15, 2004, report of Dr. Lehmann (the "Report") contains calculations and analysis of reported rates of failure in the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database for Bard's Recovery IVC filter compared to the rates of other similar filters. *See* Motion Ex. S at 22.0016. According to the Report:

> The major analysis centered around the relative risk (RR) of reporting rates between the Recovery VCF [vena cava filter] and aggregates of the other commercialized VCF, reported as a RR with a statistical significance. Other filters were also compared, and bench testing [comparative product analysis] was reported and compared to MAUDE reporting rates for filter movement.

The report does not reference litigation or claims against Bard, outline strategy or preparation for responding to claims, or contain any indicia it is for the purpose of responding to actual or threatened litigation.

Rather, it is precisely the investigation and analysis of Bard's product failures that is required by law of a medical-device manufacturer. Indeed, the very same analysis was done by Dr. Lehmann *nine months earlier* and incorporated into his *March 10, 2004,* Health Hazard Evaluation ("HHE") of a Recovery failure. *See* Ex. 1 at BVPE-01-00510993. That HHE is and was used to report these issues and is provided to, among others, the FDA.[1] Because such information is prepared for such distribution externally and beyond the legal department, it could never be protected work product.

Here, what really happened is that Dr. Lehmann began in early 2004 performing the analysis that culminated in the Report. The gathering, analysis, and use of that information went on throughout 2004. Bench testing was performed in Arizona in early 2004. *See* Ex. 2, Email from Lehmann to Passero, April 15, 2004. By April 2004, Dr. Lehmann's analysis allowed him to tell Bard's *public relations* team:

> Comparison [of the Recovery] with other filters is problematic in many ways, and we should avoid/downplay this as much as possible . . . The testing I saw in Arizona showed that altho RF was certainly within the boundaries of devices tested, in larger veins it was near the bottom. *Id.*

And, later that year, in response to another filter problem, Dr. Lehmann's work was referenced in a *December 9, 2004,* Remedial Action Plan (another unprotected document). Contrary to Bard's claim that Dr. Lehmann was retained by its legal department, that Remedial Action plan states "A consultant was commissioned by *Corporate Senior Management* [not Bard's law department] to provide an independent study of the

[1] An HHE is "a tool for classifying a voluntary recall by a firm. The evaluation guides FDA in determining the risk to the public from a defective product and appropriate actions for the firm and the FDA to take to protective public health." *See* Ex. 7, Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs), at www.fda.gov/AboutFDA/Centers, visited on December 10, 2015. Bard uses HHEs to formally analyze and document the potential ramifications of a hazard to a patient. *See* Ex. 5 at 46:14-17.

risk/benefit of the RNF in bariatric patients." *See* Ex. 3, Email from Uelmen to Keller enclosing Remedial Action Plan, at BPV-01-00435292 (emphasis added). And, as that Remedial Action Plan makes clear: "While preparing the data for this study, several unfavorable comparisons were discovered. These data comparisons are being addressed in this remedial action plan." *Id.*

Simply put, Dr. Lehmann's dealings with Bard from 2003 through 2004 demonstrate that Dr. Lehmann's failure analysis that winds up in the Report were done in the ordinary course of Bard's business, both in order to comply with Bard's required regulatory reporting and analysis *and* to assist its Crisis Communication Team with managing public relations regarding reports of Recovery device failures. The Report is not, and never was, work product and Bard's eleventh-hour efforts to manufacture a work-product claim for it should be rejected.

II. ANSWERS TO THE COURT'S QUESTIONS

Plaintiffs respond to the questions posed in CMO 2 (Doc. 249) as follows:

A. Is Dr. Lehmann's Report protected work product?

Answer: No. The Report is not subject to the work product protections of Federal Rule of Civil Procedure 26(b)(3). On its face, the Report is a straight-forward statistical analysis of publicly available facts and contains no mental impressions or strategy that one would expect in protected work product. The Report does not reference litigation, liability events, or how to deal with them. As outlined above and below, the Report was actually prepared in part to fulfill Bard's investigation obligations as a medical device manufacturer, its corporate and business responsibilities, and as part of damage control and messaging for its Crisis Communication Team and outside public relations firm. The belated contract with the Bard's legal team – entered a month before the Report was *finalized* and nearly a year after Dr. Lehmann's work began – does not somehow transform an ordinary business document into a work product privileged communication. Moreover, any possible privilege has been waived because (i) Bard is using the privilege as both sword and shield; (ii) documents in furtherance of a crime or fraud are not

privileged; and (iii) Bard failed to keep the document out of the public domain by allowing it to become a public trial exhibit in *Phillips* without any effort to protect its confidentiality during trial.

B. Is an evidentiary hearing needed?

Answer: Possibly. On Bard's own documents (and testimony), this Court could (and should) appropriately conclude that the Report is not work product. However, if the Court does not reach that conclusion on the existing evidence, Plaintiffs should be permitted to take additional discovery regarding Dr. Lehmann's and Bard's actions from February through November 2004 with respect to the gathering and processing of the MAUDE database information that is the subject of the Report. Because Bard's assertion of work product rests entirely on its claim that Dr. Lehmann was engaged by legal to create the Report, Plaintiffs in these suits should be permitted to challenge that contention with the complete evidence of what Dr. Lehmann and Bard's "Division Investigation Team" were doing in 2003 and 2004 given that Bard's internal documents show that they were analyzing and using the very same data and information that ended up in the Report.

Additionally, there has been no testimony, discovery, or document production concerning Dr. Lehmann's role at Bard throughout 2004 and the scope of dissemination and use of his final Report, along with any draft reports, regarding the Recovery® Filter. Most of the PSC and current MDL leadership were not parties or participants in the prior proceedings and have not had the opportunity even to take discovery yet. The state of the evidence from prior suits should not bind hundreds, if not thousands, of clients and dozens of lawyers under these circumstances.

C. What effect should the Court's ruling have in cases where the issue has already been decided?

Answer: Plaintiffs submit that this Court's ruling may or may not impact prior rulings. Plaintiffs anticipate that, as Bard suggests, the prior rulings will remain law of the case for those individual actions in which the issue has already been decided. However, nothing in the Court's order should preclude either party from seeking to amend or modify

existing orders on the subject, depending on the evidence developed in those individual cases and/or the law of the forum jurisdiction.

III. BACKGROUND

A. The Litigation

This litigation arises from injuries and deaths for patients who have been implanted with Bard "retrievable" inferior vena cava ("IVC") filter devices. An IVC filter is a device that is purportedly designed to "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC. Master Complaint (Doc. 364) at ¶¶ 25-26. IVC filters have been on the market since the 1960s and were traditionally utilized in patients who were at high risk for DVT/PE and could not manage their conditions with traditional medications, such as anticoagulant therapies. *Id*. at ¶¶ 28-29. However, in the early 2000s, Bard initiated efforts to expand the market for filter devices to other patient populations, such as bariatric, trauma, orthopedic, and cancer patients who were only temporarily at risk for developing blood clots. *See id.* at ¶¶ 30-31. Bard also cultivated physician interest in filter devices that could be easily removed after the risk of clotting in these new patient populations subsided. *Id.* at ¶ 32.

Bard was the first medical device manufacturer to obtain FDA clearance for marketing a "retrievable" IVC filter (the "Bard Recovery Filter") in July 2003. Bard fully released the Recovery Filter for marketing in January 2004. *Id.* at ¶ 49; *see also* Ex. 4, Recovery Filter Chronology of Events, at BPVE Filter-01-00002847.[2]

B. Bard's Obligations as a Medical Device Manufacturer

To assist with its regulatory responsibilities, the FDA places certain responsibilities on manufacturers of medical devices. For example, it requires each manufacturer to "establish and maintain procedures for receiving, reviewing, and evaluating complaints by

[2] It is important to note that all IVC filter devices at issue in this MDL are predicated on the Recovery filter, making Bard's awareness of dangers associated with the device product directly relevant in all cases.

a formally designated unit." 21 C.F.R. § 820.198. As part of this process, each manufacturer must review and evaluate complaints to determine whether an investigation is necessary. § 820.198(b). Any complaint involving "the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. § 820.198(c). Similarly, any complaint that represents "an event which must be reported to the FDA under [21 C.F.R. § 803]" must also be promptly reviewed. § 820.198(d). These "adverse events" are collected and reported in the FDA's MAUDE database. *See* Master Complaint (Doc. 364) at ¶¶ 64-65.

Similarly, medical device manufacturers have a responsibility to investigate the performance of their products and properly detect and record failures, 21 CFR § 803.1, to ensure the device is performing as it was described to the FDA when it obtained clearance, 21 CFR § 803, and to determine if the device is adulterated or misbranded (which requires investigation), 21 USC § 351, 21 USC § 321(n); 21 USC § 352(a)(f)(1),(2), (t); 21 USC § 331(a)(b); 21 USC § 360(e). They have a concomitant responsibility to audit quality systems to determine if corrective action is required. *See* 21 C.F.R. § 820.22. Manufacturers are also responsible to review MAUDE data and to determine if there is a statistically significant variance between the performance of its devices and similar devices on the market. *See* Ex. 5, Deposition of Bard Medical Director David Ciavarella, M.D., at 108:4-110:2 ("I don't think the FDA does regular trending of the MAUDE database, but I don't know for sure. But certainly it is a company's responsibility to do that.").

C. Early 2004: Bard Conducts Required Investigation of Filter Complaints

In early February 2004, Bard learned that a patient had died due to a Recovery filter breaking loose from its position in the IVC. *See* Ex. 4, at BPVEFILTER-01-00002847. According to Bard internal documents, "BPV Management Board (Division

PAT[3]) ["DPAT"] met to discuss complaints and assign resources to aggressively complete an investigation." Ex. 4 at 0002847. Dr. John Lehmann was acting medical director for Bard at the time. As part of the investigation into the death, Division and Corporate PAT worked with Dr. Lehmann. *See id.* at 00002848; Motion at 7 (detailing Dr. Lehmann's "non-legal work" for Bard). Findings associated with this investigation "led to the development of the HHE by Dr. John Lehmann." Ex. 4 at 00002848. As referenced above, that March 4, 2004 HHE included reference to comparative assessments of similar events in the MAUDE database. Ex. 1. It is clear that Dr. Lehmann had begun reviewing the comparative information as to failure rates for IVC filters from that database.

By March 2004, Bard was sitting on a major public health hazard. Its employees later described the situation as so dire in the 2004-2005 time frame that it needed to be held together with "scotch tape, smoke, mirrors, crying etc." *See* Ex. 9, *Phillips* Trial Ex. 748, March 16, 2006, Email from Greer to Hudnall. At the same time, Bard's outside public relations firm, Hill & Knowlton, began formulating a strategy and creating a "Crisis Communication Plan" to cover up the Bard's IVC Filter safety issues in the event the information was "exposed" to the media. *See* Ex. 10, *Phillips* Trial Ex. 1128, March 19, 2004, Email from Lehmann to Glass. The firm and Bard sought to include Dr. Lehmann as an expert consultant for a Crisis Communication Team; a group[4] formed for the purpose of handling Bard's public image in light of the many problems surrounding the filter. The Crisis Communication Team had nothing to do with "anticipated litigation." *See id.* A major goal for the team was to deflect attention away from the similarities between the Recovery Filter and Bard's prior conviction of 391 felonies for making fraudulent submissions and statements to the FDA. *See* Ex. 11, *Phillips* Trial Ex. 517, at BPV-17-01-00164780 ¶ 30; *see also U.S. v. C.R. Bard, Inc.*, 848

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[3] PAT stands for Product Assessment Team. The PAT has specific duties under Bard's Regulatory Affairs Manual in response to product complaints. *See* Regulatory Affairs Manual (Rev. No. 8), Ex. 6, at BVP-17-01-00844322.

[4] The Crisis Communication Team included John Lehmann, Lee Lynch, Holly Glass, Donna Passero, Janet Hudnall, Janet Jones, Kimberly Ocampo. *See* Ex. 2.

F. Supp. 287, 291 (D. Mass. 1994) (Bard "knowingly and willfully kept adverse information from the FDA, made product changes that affected the safety and effectiveness of angioplastic catheters … and illegally did testing on human beings without the required exemption from the FDA").

At the time, Dr. Lehmann was already involved in the review and analysis of the FDA MAUDE data to compare Bard's failure rates and modes to those of its competitors. In April 2004, he provided comments to the rest of the Crisis Communication Team (including General Counsel Donna Passero) regarding suggested communication materials to the public and medical community. *See* Ex. 2. Therein, he told them "[c]omparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible" – the same conclusions set forth in the December 2004 Report and obviously based on the very same analysis. *See id.* at p.1.

On April 14, 2004, Bard received a second patient-death complaint for a Recovery filter. The filter was placed on a "QA hold" (a method by which the company insures the product is not sold while being investigated for, *inter alia*, safety reasons[5]) pending completion of the remedial action plan[6] for the company. *See* Ex. 4 at 00002849. A remedial action plan was adopted. After investigation, the "QA hold" was closed, and Dr. Lehmann prepared an HHE for that event on April 27, 2004. *See* Ex. 4 at 00002851. Again, that investigation would have required him to conduct a comparative analysis of Bard's Recovery filter as against the filters of its competitors.

Later in 2004, Dr. Ciavarella took over the responsibility as medical director for Bard, but continued to utilize work from Dr. Lehmann. *See* Ex. 4 at 00002855; Ex. 5 at 63:24-65:15. Specifically, Dr. Ciavarella testified:

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[5] Although Bard saw the need to place a QA hold on the Recovery Filter, it did not notify implanting physicians of the hold and potential safety problems causing the hold to have no effect on whether products were being implanted during the hold. *See* Ex. 8, *Excerpts of* Deposition of Chad Modra, at 181:6-182:16.

[6] A remedial action plan is a plan used to respond to potential product issues. These RAPs are required by the FDA to ensure product safety. *See* 21 C.F.R. § 820.100(a)-(b).

- Dr. Lehmann was engaged to analyze the MAUDE data and to determine that there was a statistically significant increase of migration, perforation, fractures and other complications involved with the Recovery Filter when compared to other filters on the market. Ex. 5 at 179:16-180:14.
- Dr. Lehmann's findings were used in the company's HHEs. *Id.* at 286:2-16.
- Dr. Ciavarella was provided a copy of the final Lehmann Report to assist him as the medical director for his preparation of an HHE to fulfill Bard's regulatory responsibilities. *Id.* at 286:13-23.

It was apparent from Dr. Lehmann's HHEs on the Recovery filter and his communications with the Hill & Knowlton Crisis Communication Team (of which Bard's general counsel Donna Passero was a member) that his review and analysis of the FDA MAUDE information to compare the failures and modes of failures of Bard's Recovery Filter as against similar filters of other manufacturers was producing dramatically bad results for Bard. And, Plaintiffs posit, faced with an upcoming report that would compile this bad information in a summary format, Bard's legal department decided to make an eleventh-hour attempt to cover up Dr. Lehmann's findings – signing him to a "consulting agreement" with the legal department to do the work and analysis he was already performing. But, someone forgot to tell their cover-up plan to the business people. And, on December 9, 2004 – weeks after the Bard legal contract with Dr. Lehmann – a Bard Remedial Action Plan ("RAP") stated that Dr. Lehmann "was commissioned by *Corporate Senior Management* to provide an independent study of the risk/benefit of the RNF in bariatric patients." *See* Ex. 3, at BPV-01-00435292 (emphasis added). That Remedial Action Plan further stated that: "While preparing data for this study, several unfavorable comparisons were discovered. These data comparisons are being addressed in this remedial action plan." *Id.* The RAP went on to describe precisely the study that Dr. Lehmann had undertaken (and was ultimately described in the report) and to summarize the findings of that study (though not with the detail of the actual Report).[7]

[7] The RAP indicates that a "Division Investigation Team (DIT) was assigned to review the data associated with the identification of the problem (above)" and that "[t]he DIT completed a review of all IVC Filter MDRs found in the MAUDE from Q1 200 [sic] through Q3 2004." *Id.* at BPVE-01-00435398. Documents regarding this review and the work of the DIT have not been produced by Bard.

On December 9, 2004, six days *before* the "final" Report was sent to Donna Passero, Bard's Division PAT "reviewed internal complaint data, literature, bench testing results, sales data and consultant reports on MAUDE report rates for the RNF." Ex. 4 at 00002857.[8] Thus, it appears that the Report and its underlying information was provided to Division PAT just days before Dr. Lehmann finalized it.

Dr. Lehmann issued his final Report on December 15, 2004. Motion Ex. S. It references no litigation or claim against Bard, contains no strategy for dealing with lawsuits or claims, and makes no recommendations as to how to deal with lawsuits. It is a statistical report that demonstrates, based on the publicly available data, that Bard's Recovery filter failed at an alarming rate (and rates) relative to its competitors.

Two days later, Dr. Ciavarella prepared an HHE (Exhibit U to the Motion) "as part of [his] duties as the Medical Director and within which—from which [he] gained information and knowledge from having read Dr. Lehmann's Report dated December 15." Ex. 5 at 287:16-24. Dr. Ciavarella testified that he received the Report "without restriction" as to its use and was never told that he could not cite its contents in the HHE he was preparing. *Id.* at 286:24-287:8. He further testified that he was permitted to use his discretion as to how to utilize the Report, and *was never instructed that the Report was secret or prepared in anticipation of litigation*. *Id.* at 287:9-12; *cf.* Motion Ex. P at ¶ 11 (stating Bard employees who received the Report were instructed that it was confidential).

And, even in January 2005, another RAP references the Report and made extensive use of and citation to the information in it. *See* Ex. 13, Recovery Filter Migration, Remedial Action Plan, January 4, 2005.

D. Judge Jones Hears the Evidence in Context and Overrules Bard's Privilege Claim

Earlier this year, in the only case in which a judge has had the benefit of a full evaluation at trial of the evidence and course of dealings of Dr. Lehmann's history

[8] RNF is Bard's internal moniker for its Recovery filter.

regarding this product, U.S. District Court Judge Robert C. Jones found that Dr. Lehmann's Report was *not* protected work product:

> Counsel has objected to introduction of this Report from a witness that we've already heard testimony from by deposition [Dr. Lehmann] because labeled at the top it says Work Product. That means it's tendered to the attorney, the attorney hired him. We normally protect Work Product. We want to encourage communication, just like attorney-client confidential communication between attorney and hired consultant. But we already have established that this report is referenced in some of -- in fact some of the ratios above are referenced in an HHE issued by Dr. Ciavarella which references these figures. We also have intimation, not proof yet, that this Report was attached to the HHE. So what this means in the Court's mind is that this report was not strictly given to the lawyers as Work Product, potentially for retaining the expert as an expert, the outside consultant as an expert in the case. This was also given to the company. What the company was aware of when it revised or gave IFUs or instructions to doctors is relevant to the question of defect and warnings. Therefore, I have ruled that the attorneys cannot protect or prevent this document from coming into evidence under the Work Product Rule because it is now clear, and the foundation has been established, that whether Mr. Carr was aware of it or not, certainly the company was aware of this Report, and it was prepared partially for their benefit, not just the attorneys. Therefore, I have overruled the Work Product exemption, and, therefore, this current objection is overruled.

Motion Ex. AA at 308:17-309:23.

Judge Jones rejected Bard's effort to conceal the Report by belatedly giving Dr. Lehmann a contract with the law department. He found that the genesis of Dr. Lehmann's work, findings, and Report, and its use by Bard in discharging its corporate responsibilities, demonstrated that the Report was prepared in the ordinary course of business. This Court should, likewise, reject Bard's claims.

IV. ARGUMENT

The work product doctrine, codified in Federal Rule of Civil Procedure 26(b)(3), protects from discovery "documents and tangible things prepared by a party or his representative in anticipation of litigation." *In re Grand Jury Subpoena (Mark Torf/Torf Envtl. Mgmt.)*, 357 F.3d 900, 906 (9th Cir. 2004) (quoting *Admiral Ins. Co. v. United States District Court*, 881 F.2d 1486, 1494 (9th Cir. 1989)).

To qualify for work-product protection, documents must: (1) be "prepared in anticipation of litigation or for trial" and (2) be prepared "by or for another party or by or

for that other party's representative." *In re Grand Jury Subpoena*, 357 F.3d at 906. It is undisputed that the Report was not prepared exclusively for litigation. In the Ninth Circuit, "[i]n circumstances where a document serves a dual purpose, that is, where it was not prepared exclusively for litigation, then the 'because of' test is used." *United States v. Richey*, 632 F.3d 559, 567-68 (9th Cir. 2011); *see also City of Glendale v. Nat'l Union Fire Ins. Co. of Pittsburgh, PA*, 2013 WL 1797308, at *12 (D. Ariz. Apr. 29, 2013) ("This 'because of' standard applies when a document could be characterized as having been prepared for multiple purposes, such as for purposes of conducting the ordinary course of business, or because of the prospect of litigation."). Under this test, a document is only eligible for work product protection if, "in light of the nature of the document and the factual situation in the particular case, the document can be fairly said to have been prepared or obtained because of the prospect of litigation." *In re Grand Jury Subpoena*, 347 F.3d at 907.

"In applying the 'because of' standard, courts must consider the totality of the circumstances and determine whether the 'document was created because of anticipated litigation, and would not have been created in substantially similar form but for the prospect of litigation.'" *Richey*, 632 F.3d at 567-68 (emphasis added). When there is a true independent purpose for creating a document, work product protection is unlikely. *See In re Grand Jury Subpoena*, 357 F.3d at 908. The analysis becomes more muddled if the document's dual purposes are "profoundly interconnected," *id.*, but other than Ms. Passero's vague and self-serving reference to risk assessment there is no evidence that the Report was contemplated or used for any litigation purpose during the 11-plus years since its creation.

A. The Report was prepared in the ordinary course of Bard's business.

Documents and other materials created in the ordinary course of business are not attorney work product. *See* Fed. R. Civ. P. 26(b)(3), Advisory Committee Notes; *S. Union Co. v. Sw. Gas Corp.*, 205 F.R.D. 542, 549 (D. Ariz. 2002) ("[T]here is no work product immunity for documents prepared in the ordinary course of business prior to the

commencement of litigation.") For example, in *Richey*, there was no work product protection for an appraisal report attached to a federal income tax report. 632 F.3d at 568. The appraisal Report was prepared as required by law, and there was no "evidence in the record that Richey would have prepared the appraisal work file differently in the absence of prospective litigation." *Id.*

Similarly, in *Marceau v. I.B.E.W.*, 246 F.R.D. 610, 614 (D. Ariz. 2007), the parties disputed whether an audit conducted of a business's processes and employer relations was work product. The court noted that although litigation may have been anticipated,

> in light of the history of the issues addressed in the Report it is reasonable to believe that the Report would have been prepared in the absence of anticipated litigation. In addition, the fact that litigation was not imminent tends to support the argument that the Report was not prepared in anticipation of litigation. . . . Finally, the Report's prefatory statements, findings, and recommendations make no reference to a fear of anticipated litigation.

Id. For these reasons, the audit report was not subject to work product protection. *See id.*

As described above, Dr. Lehmann was engaged as a medical director to assist with Bard's product remedial action. And, as also described above, Bard has significant obligations to investigate and to report product failures, including conducting comparisons to competitor products. This is Bard's ordinary business work, not work done in anticipation of litigation. Bard has a Regulatory Affairs Manual (revised in October 2004 before Dr. Lehmann filed his Report) governing Bard's required response to patient complaints and "product remedial actions." *See* Ex. 6; *see also* Regulatory Affairs Manual (Rev. 9), Ex. 12. The purpose of the manual is "to provide a standard for the development and implementation of a remedial action plan in response to a potential product issue, and to establish a process for the review and approval of that plan." Ex. 6 at BPV-17-01-00044320. The 16-page manual is complete with information concerning Bard's responsibilities to the FDA for recalls and how to classify certain types of actions. Importantly, it talks about Bard's PAT (Product Assessment Teams). The Division Product Assessment Team (Division PAT) is responsible for evaluating product problems

which could lead to some type of remedial action and for developing a proposed action plan to deal with such problems. At a minimum, the team shall include the department heads (or designees) of RA, marketing, manufacturing, RND/engineering and shall be chaired by the division head of QA. ***"The assigned medical director should also be considered a member of a the Division PAT and should be consulted throughout the remedial action assessment process."*** Ex. 6 at BPV-17-01-00044322 (emphasis added).[9]

Throughout 2004, Dr. Lehmann worked as the medical director for Bard in his capacity as a member of the Division PAT described above. He also served as a vocal member of Bard's Crisis Communications Team. Both of these free-standing functions would be conducted irrespective of any anticipation of litigation. His work was done as part of Bard's ongoing regulatory responsibility, and the ordinary (for Bard) course of public relations business. Thus, the work product privilege cannot shield his work from use in this case. *See* Motion Ex. AA. (Judge Jones' ruling).

It is no answer that Dr. Lehmann was given a contract with the law department and, purportedly, his work became more extensive when preparing the "final" Report. Bard's actual use of the Report is the decisive factor. Bard's PAT used the Report to develop its December 9, 2004 and January 4, 2005, Remedial Action Plans and the December 12, 2004, HHE, all of which are part and parcel of Bard's regulatory responsibilities. *See* 21 C.F.R. § 820; Ex. 5 at 287.

Moreover, Dr. Lehmann's contention that the Report was more extensive than prior work he performed for Bard is suspect at best. Dr. Lehmann used his prior research on all the other complaint investigations to formulate his final Report. His Report also culled through the FDA's MAUDE data and product sales figures to conduct the analysis present

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[9] There is a corresponding "Corporate PAT" which is responsible for reviewing the Division's proposed action plan and providing recommendations regarding the plan to the VP, corporate regulatory sciences. The corporate PAT is comprised of representatives from corporate regulatory affairs, medical affairs, operations, and law and is chaired by the VP, corporate quality assurance, or his or her designee. *See* Ex. 6 at BPV-17-01-00044323. As with the Report, the fact that Bard's Law Department is consulted on matters does not transmogrify all of Bard's daily work into protected work product.

in the final Report, work he began in February 2004. *See* Ex. 1 at BPV-01-00310993 (noting that Dr. Lehmann reviewed the MAUDE data and medical literature to prepare HHE). This same data was provided in the form of a "consultant report" to Bard's Division PAT operating per its Regulatory Affairs Manual. *See* Ex. 4 at 00002857. Similarly, Dr. Lehmann's work as a member of Bard's Crisis Communication Team was not helping Bard in anticipation of litigation; it was helping Bard to manage its message and maintain its profitability. *See* Ex. 11 at BPV-01-00164737 ("The proliferation of unfavorable press . . . can cause an onslaught of negative activity . . .stock prices may plummet, analysts may downgrade the affected company's rating….").

Bard has produced no evidence that the Report was actually used in any way to assist with risk assessment, litigation strategy, or for any litigation purpose. Given the Report's liberal use in Bard's public relations messaging and regulatory reporting, it is more than "reasonable to believe that the Report would have been prepared in the absence of anticipated litigation." *Marceau*, 246 F.R.P. at 614.

Ms. Passero's testimony that Dr. Lehmann's work for the law department was wholly different from his prior work is not supported by the documents produced before and after the December 15, 2004 Report. *Compare* Motion Ex. S with Exs. 2, 3, 13 (Jan. 4, 2005 Remedial Action Plan attaching Lehmann Report). Moreover, despite being a member of Bard's PAT, Ms. Passero had almost no recollection or understanding of Dr. Lehmann's pre-law-contract work for Bard or the regulatory requirements under which he and the company were operating. *See* Motion Ex. O, at 27:18-20 ("I don't know what other work [Lehmann] did for the company other than that he was retained to be an acting medical director."); 33:15-34:17 ("I'm not a regulatory lawyer." "You're referring to things that are regulatory in nature, and I don't know or don't remember."); 43:14-18 (noting that Passero was not familiar with federal regulatory reporting requirements); 55:3-8 ("I don't know. It's not my department. I don't know what [Bard does] with [complaint files]."). Perhaps it was Ms. Passero's *impression* during the *Alexander* hearing some 10 years after the subject events that Dr. Lehmann was doing a separate

project per his contract with the Law Department. But her impression is wrong and uninformed. Not only did she repeatedly profess ignorance concerning the extent of Dr. Lehmann's pre-November 2004 work for Bard, *see id.*; *see also id.* generally at 44-59 (demonstrating unfamiliarity with February-April Lehmann work), but discussion of Lehmann's prior 2004 work is conspicuously absent from her affidavit submitted in support of Bard's Motion. *See* Motion Ex. P.

Just because the left hand doesn't know what the right is doing does not mean the right hand isn't doing anything. Lehmann's extensive prior work was utilized to draft the Report *and* to assist Bard in its required product analysis. *See* e.*g.*, Exs. 2-4, 13.

Finally, although Bard witnesses state that the company was anticipating litigation, there is no evidence that litigation was "imminent." Indeed, while Lehmann's consulting work under the legal department purportedly began in November 2004, Bard did not institute a litigation hold until December 2004. *See* Ex. 14, Transcript of October 29, 2015, proceedings, at 150:18-24.; Ex. 15, November 20, 2015, letter from Lerner to Stoller, at 2. This casts further doubt upon Ms. Passero's testimony as in-house counsel that she anticipated litigation; if that were true, a litigation hold should have been put in place prior to the engagement of Dr. Lehmann by Bard legal.

The standard governing when a litigation hold must issue is the same as the test used to determine if the product deserved work product protection: reasonable anticipation of litigation. *See Melendres v. Arpaio*, 2011 WL 6740709, *2 (D. Ariz. 2011) (citing *In Re Napster, Inc. Copyright Litigation*, 462 F. Supp. 2d 1060, 1070 (N.D. Cal. 2006) ("[T]his amply demonstrates that there was a reasonable probability of litigation.")); *see also Zubulake v. UBS Warburg, LLC*, 220 F.R.D. 212, 218 (S.D.N.Y. 2003) (stating "that once a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a litigation hold to ensure the preservation of relevant documents").

Under this standard, Bard was not *acting* like a company anticipating imminent litigation in November 2004 when it changed Dr. Lehmann's contract over to the Law Department. Bard should not be permitted to have it both ways.

Bard's reliance on the Court's decision in *Bickler v. Senior Lifestyle Corp.*, 266 F.R.D. 379 (D. Ariz. 2010), to shield the Report as work product is misplaced. In *Bickler*, a nursing home resident fall investigation was undertaken at the direction and on the advice of counsel and was "more extensive than inquiries routinely made after incidents at the nursing home." *Id.* at 383. Here, Dr. Lehmann's work was well underway long before he was given a contract with the Law Department and before Bard initiated the litigation hold. Bard had an independent responsibility to conduct the very analysis it commissioned Dr. Lehmann to perform, *see* 21 C.F.R. § 820.22, and the Report contains the very analysis he had provided to Bard during the Spring and Summer of 2004. And the Report was widely quoted in Bard's HHE disseminated a mere two days later. *See* Motion Ex. U. It was also attached to Bard's January 4, 2005, RAP. Ex. 13[10]

In addition, Doug Uelmen, a Bard employee, was privy to Dr. Lehmann's work and was using Dr. Lehmann's investigation results *six days prior* to the Lehmann Report being published and delivered to the legal department. *See* Ex. 3. If the Lehmann Report was commissioned solely in anticipation of litigation, provided directly and exclusively to the Law Department, as Bard and Dr. Lehmann now contend, and not created in the normal course of Bard's business of evaluating health hazards, how is it that Mr. Uelmen was using the Report's contents to perform a routine safety investigation *before* the Report was finished and sent to the Law Department?

A side-by-side comparison of the contents of Uelmen's December 9 safety report and the Lehmann's Report shows that Mr. Uelmen was utilizing the Lehmann Report for something other than litigation before the Report was even finalized; he was developing a

[10] For unknown reasons, the version of the RAP attached to Defendant's Motion , Ex. T, omits this attachment.

new Remedial Action Plan as required by both Bard's Regulatory Affairs Manual and 21 C.F.R. Part 820:

Contents That Are the Same Between Uelmen's Remedial Action Plan and Lehmann's Report:	**December 9, 2004 - Uelmen (REVISED) Remedial Action Plan**	**December 15, 2004 - Lehmann Report**
Comparison Devices	Same as Lehmann Report, see all Tables on pp. 6-14	Same as Uelmen, pp. 2, sec. 1
Sources of Comparative Data	Same as Lehmann, Sec1.1, 1.2, & 1.4	Same as Uelmen, pp. 4-5, sec. 2(a), 2(b) & 2(c)
Data normalized to show AEs per 100,000	Same as Lehmann, see pp. 7 above Table Three	Same as Uelmen, pp. 2, sec. 3.
Normalization of Data in the same categories: • Fatalities with migration • Non-Fatal migrations • Vena Cava perforations with Fractures • All Deaths	Same as Lehmann, at Tables: 2.2., 2.5, 2.7, 2.8	Same as Uelmen, see pp. 2, sec 4.
Statement of Relative Risk When Compared to: • All IVC filters • Retrievable IVC filters • All IVC Filters as a group	Same as Lehmann, at Tables 2.2 – 2.9	Same as Uelmen, see pp. 2, sec. 5.

It strains credulity to suggest the Lehmann Report was created in anticipation of litigation and provided only to Bard Legal and select non-legal employees when there are so many similarities between what Dr. Lehmann developed and the documents being circulated in the ordinary course of Bard's business days before the Report was delivered to its Law Department.

Nor does anticipating litigation following injuries associated with a manufacturer's product always or automatically qualify an in-house report as work product. *See Soeder v. General Dynamics Corp.*, 90 F.R.D. 253 (D. Nev. 1980). There is a competing policy concern under these circumstances for a manufacturer to protect future users of the product, improve the product, guard against adverse publicity, protect economic interests, and maintain prospect for sales in the future. *Soeder*, 90 F.R.D. at 255. Ms. Passero herself admits that she was not protecting Dr. Lehmann's work during the time she

allegedly converted Bard's relationship from a non-legal to a legal consultant so that patient safety could be addressed. Motion Ex. O at 29:24-30:11, 31:19-23.

Perhaps most telling of all is that Dr. Lehmann's final Report is the only collection of MAUDE data analysis produced by Bard. If Bard has an independent responsibility to analyze the MAUDE data trends (Ex. 5, at 108:4-110:20), and Dr. Lehmann's Report is the only such analysis from this critical time frame, any litigation-based use is merely incidental and cannot create a work product privilege. *See Richey*, 632 F.3d at 562-68 (noting that if document would be created without litigation, the document is not privileged).

B. Calling the Report work product is not enough

Bard makes much of the fact that the Report says that it is produced pursuant to contract (with the law department). Yet simply calling something work product does not make it so. The Court must look to the actual character of the document and its use as opposed to labels provided by the party asserting protection. Generally, work product includes any documents "prepared by agents of the attorney in preparation for litigation." *Richey*, 632 F.3d at 567. Factor that have been considered in determining whether a document is truly work product include: (1) timing of the document's creation (was litigation pending or apparent?), *see Marceau v. I.B.E.W.*, 246 F.R.D. 610, 614 (D. Ariz. 2007) ("[T]he fact that litigation was not imminent tends to support the argument that the Report was not prepared in anticipation of litigation."); (2) document required by law regardless of litigation, *see id.* at 614 (holding that "in light of the history of the issues addressed in the Report it is reasonable to believe that the Report would have been prepared in the absence of anticipated litigation."); *Richey*, 632 F.3d at 568 ("Had the IRS never sought to examine the Taxpayers' 2003 and 2004 federal income tax returns, the Taxpayers would still have been required to attach the appraisal to their 2002 federal income tax return. Nor is there evidence in the record that Richey would have prepared the appraisal work file differently in the absence of prospective litigation."); and (3) document includes attorney opinions, *see Yurick ex rel. Yurick v. Liberty Mut. Ins. Co.*,

201 F.R.D. 465, 472 (D. Ariz. 2001) ("There are two types of work product recognized, ordinary work product and opinion work product, and generally opinion work product, including mental impressions, conclusions, opinions or legal theories, is entitled to nearly absolute protection.").

Here, the Report contains no indicia of work product, other than being labeled the product of a contract with the Law Department. According to Magistrate Judge Toomey from the Middle District of Florida, the Report has "no hint" of a litigation purpose about it. There is no discussion of strategy (at least as it relates to legal work), litigation, or attorney thought processes. *See* Ex. 16, *Payne and Tillman v. C.R. Bard, Inc.*, Case No. 3:13-CVMMH-JBT, Order dated March 28, 2914, at 15.[11]

The Report simply contains the factual information (collected as part of otherwise-required product investigation) in a format and with findings unfavorable to Bard in defense of its product. It is not work product.

C. If the Report was ever privileged, the privilege was waived

1. Bard cannot use the privilege as both sword and shield

A party may not selectively disclose some work product documents beneficial to its claims while withholding other documents that potentially harm them. This voids the work product privilege: "'The attorney-client privilege and work product immunity may not be used both as a sword and a shield. Where a party raises a claim which in fairness requires disclosure of the protected communication, [these protections] may be implicitly waived.'" *Torres v. Goddard*, 2010 WL 3023272, at *6 (D. Ariz. July 30, 2010) (quoting *Verizon Cal. Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, 266 F. Supp. 2d 1144, 1148 (C.D. Cal. 2003)).[12] Waiver of privilege "protect[s] against the unfairness that would result from a privilege holder selectively disclosing privileged communications to an

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[11] Judge Toomey's recommendations were affirmed by District Court Judge Howard. *See Payne and Tillman v. C.R. Bard, Inc.*, Case No. 3:13-cv-222-J-34 JBT, Order dated March 11, 2015, Ex. 17.

[12] Unlike here, the documents at issue in *Torres* were not material, so the court found no waiver. 2010 WL 302327 at *7.

adversary, revealing those that support the cause while claiming the shelter of the privilege to avoid disclosing those that are less favorable." *Tennenbaum v. Deloitte & Touche*, 77 F.3d 337, 340-41 (9th Cir. 1996); *see also Arizona Dream Act Coalition v. Brewer*, 2014 WL 171923, at *6 (D. Ariz. Jan. 15, 2014) (refusing to allow defendants to "selectively disclose privileged communications for their own benefit"; once defendants invoked attorney-client privilege they could not later describe the advice or argue that decision was made on advice of counsel).[13]

Here, Bard has indicated in business documents (including its December 9, 2004, REVISED RAP and December 17, 2004 HHE) that it performed its required product analysis by hiring an independent medical consultant (Dr. Lehmann) who was "commissioned by Corporate Senior Management to provide an independent study of the risks and benefits of the [Recovery Filter] in bariatric patients." Ex. 3 at BPVE-01-00435296-97. Bard's selective quotation of the Report is evident from numerous examples. The December 17, 2004 HHE, sent just two days after the "final" Report was issued, and the January 4, 2005 RAP, both extensively quote and rely upon Dr. Lehmann's analysis with the stated conclusion that Bard placed a significant emphasis on the product's safety and efficacy in bariatric patients. *See* Motion Ex. U; Ex. 3. Yet when Dr. Lehmann's Report (Motion Ex. S) is examined, it does not use the word bariatric once, nor focus on any particular condition of patients who have suffered injury due to having a Bard filter failure, nor analyze any of the so-called benefits of the Recovery device. Bard told the FDA and the medical community that the Recovery failed at the same rate as competition models while knowing from the Report that this was not true.

[13] While the sword/shield waiver is typically discussed in the context of the attorney-client privilege, the fairness principle upon which it is based applies with equal force to claims of work product privilege. *See Bittaker v. Woodford*, 331 F.3d 715, 718-22 & n.6 (9th Cir. 2003) ("Although our decision is couched in terms of the attorney-client privilege, it applies equally to the work product privilege, a complementary rule that protects many of the same interests.").

See Ex. 2. Denying Plaintiffs the use of the actual Report to correct this misapprehension would be wholly unfair and allow Bard to use the Report as both sword and shield.

2. The crime fraud exception destroys Bard's privilege claim.

The crime-fraud exception provides another basis for finding the Lehmann Report is not protected. The Report was a centerpiece of an ongoing fraudulent scheme by Bard to push its retrievable IVC filters through FDA clearance onto the market, and then cover up and misrepresent to the public the risks, injuries, and deaths caused by its products. Although discovery into Bard's scheme—especially as to Bard's fraudulent misrepresentations to the FDA during the original Recovery filter 510(k) process and its post-market reporting to the FDA of injuries and deaths caused by its IVC filters—is just beginning, Plaintiffs have sufficient evidence of Bard's criminal and fraudulent scheme to establish a prima facie case that the Report was used to further a crime or fraud such that the attorney-client and work product privileges cannot apply.

Attorney-client communications and attorney work product made in furtherance of a crime or fraud are not privileged. *United States v. Zolin*, 491 U.S. 554, 563 (1989); *In re Grand Jury Proceedings (The Corporation)*, 87 F.3d 377, 381 (9th Cir. 1996.

To invoke the crime-fraud exception, the moving party must show that the communications were in furtherance of an intended fraud or crime and that there is some relationship between the communications at issue and the misconduct. *In re Grand Jury Proceedings*, 87 F.3d at 380. Thus, the moving party first must establish that "the client was engaged in or planning a criminal or fraudulent scheme when it sought the advice of counsel to further the scheme," *id.* at 381, and then must show that the communications are sufficiently related to and were made in furtherance of the intended or ongoing crime or fraud, *In re Napster, Inc. Copyright Litig.*, 479 F.3d 1078, 1090 (9th Cir. 2007) *abrogated on other grounds by Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100 (2009).

The movant need only establish "reasonable cause" to believe that the legal services were utilized in furtherance of the ongoing unlawful scheme. *See In re Grand Jury Proceedings*, 87 F.3d at 381. The Ninth Circuit has defined "reasonable cause" as

"more than suspicion but less than a preponderance of evidence." *United States v. Chen*, 99 F.3d 1495, 1503 (9th Cir. 1996). In other words, "the moving party must make a prima facie case" that a crime or fraud occurred and then provide some evidence that there is a "reasonable basis" to believe that the attorney's services were used to further the crime or fraud. *Cohen v. Trump*, 2015 WL 3617124, at *12 (S.D. Cal. June 9, 2015) (slip op.); *Clark v. United States*, 289 U.S. 1, 15 (1933); *In re Grand Jury Proceedings*, 87 F.3d at 381; *accord Buell v. Superior Court*, 96 Ariz. 62, 64, 391 P.2d 919, 924 (1964).

Rather than establishing every element of a crime or fraud, the moving party must only show it has "a factual basis adequate to support a good faith belief by a reasonable person that wrongful conduct sufficient to invoke the crime or fraud exception to the attorney-client privilege has occurred." *Caldwell v. Dist. Court*, 644 P.2d 26, 33 (Colo. 1982); *see also Zolin*, 491 U.S. at 572; *Cohen*, 2015 WL 3617124, at *12 (quoting *Clark*, 289 U.S. at 15)).[14]

a. Dr. Lehmann's work for Bard was part of its criminal and fraudulent scheme to sell a dangerously unsafe medical device.

Bard has a long history of misrepresenting the safety and efficacy of its products in correspondence and filings with the FDA, both with its IVC filters and with other products.[15] A full discussion of that history, including Bard's fraudulent

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[14] The crime-fraud exception applies equally to the attorney-client communication and work product privileges because there is "no reason to apply a different standard for attorney work product." *In re Richard Roe, Inc.*, 68 F.3d 38, 40 n.2 (2d Cir. 1995) (citing *In re Grand Jury Proceedings*, 604 F.2d 798, 803 (3d Cir. 1979)).

[15] Bard pled guilty to 391 criminal charges in 1993 for filing false and misleading reports with the FDA regarding the lack of testing and known hazards of its Probe Heart Catheters. The catheters were recalled in 1990 after being linked to multiple serious injuries and deaths. Six Bard officers and managers were also indicted. Bard's sentence included $61 million in fines for violating the FDA Act, the False Claims Act and the Civil Monetary Penalties Law. *U.S. v. C.R. Bard*, 848 F. Supp. 287 (D. Mass. 1994). And contemporaneous with the misconduct at issue in this case, Bard's decision to put other dangerously unsafe products on the marketplace has spawned two other MDLs involving thousands of injuries and lawsuits. *See In re Kugel Mesh Hernia Patch Products Liability Litigation*, MDL 1842 (D.R.I.); *In re: C.R. Bard Inc. Pelvic Repair System Products Liability Litigation*, MDL 2187 (S.D.W.V.). Bard also agreed to pay $48.2 million in 2013 to resolve a qui tam lawsuit arising out of the False Claims Act and questionable sales and marketing practices over a period of years in its brachytherapy

misrepresentations to the FDA to obtain 510(k) approval for its IVC filters, will be the subject of later briefing after discovery into that history is more complete. For present purposes, however, it is necessary to focus on a different aspect of Bard's scheme to sell its dangerous products to unsuspecting doctors and patients: its cover up of adverse testing, injuries, and deaths associated with its filters. Bard's actions not only fit any reasonable definition of "fraudulent"[16] but constitute a violation of multiple federal criminal statutes. Plaintiffs' prima facie case that Bard engaged in a scheme is as follows:

- On February 9, 2004, Bard received the first reported death associated with its Recovery Filter that was implanted in a patient who underwent bariatric surgery. *See* Ex. 4 at BPVE-FILTER-01-00002847.
- In response to what Bard itself called a "crisis" regarding the abysmal safety records of the Recovery Filter, Bard formed, with the help of Dr. Lehmann, the internal "Crisis Communication Team" described above. *See* Ex. 11 at BPV-17-01-00164734, ¶ 30; Ex. 2.
- On April 23, 2004, Bard's Vice President of Quality Assurance, Christopher Ganser, sent an email noting that the Recovery Filter's reported failure rates "did not look good compared to permanent filter" and promised to remove the filter from the market if its reported death rate became "significantly greater than the rest of the pack." *See* Ex. 18. Bard did not disclose this to the FDA, doctors, or patients, and despite the acknowledgment by Dr. Lehmann and other members of the Crisis Communication Team that comparisons of the Recovery to other IVC filters were "problematic" because the Recovery's migration rates were significantly higher, it did not issue a recall of the Recovery.
- On July 9, 2004, analysis of failure rates showed the Recovery Filter had a failure rate that was 28 times higher than all other IVC filters. Ex. 19, Draft Updated HHE dated July 9, 2004. Bard did not disclose this to the FDA, doctors, or patients or recall the filter.
- The Report found that the "[r]eports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters." "These deficiencies were all statistically significant…" and were "significantly higher than those for

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cancer-treatment unit. *See Darity v. C.R. Bard, Inc.*, Civ. Action No. 1:06-cv-0208-SCJ (N.D. Ga.).

[16] Whether Bard's scheme to put an unsafe product on the market and keep it there constitutes a cause of action for fraud under the law of a particular jurisdiction is irrelevant; courts across the country have adopted and applied a broad interpretation of the crime-fraud exception to a wide range of misconduct involving deception or quasi-criminal activity. *See Diamond v. Stratton*, 95 F.R.D. 503, 505 (S.D.N.Y. 1982) (stating that limiting crime-fraud exception only to fraud would be too narrow and holding that it can be applied to wide range of intentional torts; quoting 8 Wigmore, Evidence § 2298, at 577 (McNaughton rev. 1961)).

other removable filters." Motion Ex. S. Thus Bard had by then concluded that the Recovery filter's reported rates for perforation, death, migration and fracture were in fact substantially higher than all devices. Again, this was not reported, no warning was issued, and the Recovery was not recalled.

- Bard witnesses have testified that they were aware that the Recovery Filter was more likely to migrate than the SNF if challenged by clot. *See* Ex. 20, Excerpts of Transcript of Deposition of Chris Ganser, V.P. of Regulatory Science and Clinical Affairs, at 90:11-92:3. By December 2004, according to Bard's own safety procedure the Recovery Filter was deemed not reasonably safe for human use given its failure rate. *See* Ex. 21, Excerpts of Transcript of Deposition of Douglas Uelmen, Jr., former V.P. of Quality Assurance, at 330:24, 333:01-344:24. But still no reporting, no warning, no recall.

- By 2011, Bard knew that the Recovery Filter has a reported fracture rate 55 times higher than the SNF. *See* Ex. 22, *Phillips* Trial Ex. 760, Email from Hudson to Bovee, June 28, 2011. But Bard has still *never* reported this information to the FDA, never warned doctors and patients of the exponentially higher failure rates associated with the Recovery, and never recalled its product, which is still installed in thousands of unsuspecting patients.

Once Bard learned that the Recovery Filter's safety profile was no longer substantially similar to its predicate device—the SNF— it knew that its product was not in compliance with FDA regulations and must be voluntarily recalled. *See* 21 C.F.R. § 7; *see also* 21 C.F.R. §§ 806, 810. Bard's concealment of this information from the FDA, and instead hiring a PR firm and Dr. Lehmann to help it explain away the problems with the Recovery, violated several federal criminal and regulatory statutes, including: 18 U.S.C. § 371, Conspiracy; 18 U.S.C. § 1001, False Statements to the FDA; 18 U.S.C. § 1341, Mail Fraud; 21 U.S.C. § 333(b), Failure to Submit Medical Device Reports; and 21 U.S.C. §331(a), Adulterated Products (for distributing a medical device despite knowing that the device was not substantially equivalent to a predicate medical device).

Although discovery is ongoing on this subject, the evidence outlined above establishes a prima facie case that Bard engaged in misconduct. Items used in furtherance of that misconduct are not privileged under the crime-fraud exception.

b. <u>The Report was created in furtherance of Bard's criminal and fraudulent scheme</u>.

Dr. Lehmann's work for Bard and his Report were crucial elements of Bard's fraudulent scheme to sell and profit from an unsafe medical device. As a member of

Bard's Crisis Communication Team, Dr. Lehmann advised Bard what to "downplay" with regard to this line of filters and emerging risks known only to Bard.

> "Bottom line: good filter, severe case, bad outcome, deep regret. This is the simple story we should repeat again and again. Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. Ex. 2.

And downplay they did. Bard implemented the Crisis Communication Plan created by Hill & Knowlton to avoid having to disclose the Recovery Filter safety, FDA deception, and false marketing issues that were front and center for Dr. Lehmann as early as April 2004. Dr. Lehmann counseled Bard to be "very careful" about discussing physician training because "It's not . . . what you told the FDA, but what you are actually currently doing." Dr. Lehmann was a primary engineer of Bard's concealment:

> When pressed, we simply paraphrase what was said in the Health Hazard, that "Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device." Ex. 2.

In 2004, Bard and Dr. Lehmann knew that a comparison of their devices with other devices on the U.S. market would be "problematic" for Bard. Plaintiffs submit that this is why Bard made the decision in November 2004 for the Bard Legal Department to "hire" Dr. Lehmann and to start stamping his work "attorney work product." Despite this effort, privileges do not extend to the deceptive, fraudulent, and criminal conduct that Plaintiffs have described.[17]

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[17] It is important to note that Plaintiffs seek application of the exception to *one* document which was a centerpiece of Bard's scheme to cover up evidence of the failure rates, injuries, and deaths associated with the use of its product. The Report found that for the Recovery Filter the "higher rate of death reports seems related to filter movement and filter embolization associated with death." Motion Ex. S at 01019804. And bench testing showed that "the Recovery filter has the least ability to resist migration of all tested [IVC filters] at larger simulated IVC diameters." *Id.* at 01019807. These findings and other poor bench testing for migration resistance were "of concern," *id.*, and when combined with the link between failures and deaths constituted "two significant signals" which "urgently warranted" further investigation, *id.* at 01019790. But Dr. Lehmann then tried to "substantially temper[]", *id.* at 01019804, these conclusions with a litany of excuses and rationalizations critiquing the dataset, the reporting of the data, and other similar problems with competitors' products. *Id.* at 01019809-20 ("Appendix A: Problems with quantitative interpretation of MAUDE and sales data"). These "potential biases and confounding factors" meant that risk assessments of the Recovery Filter were probably "erroneously high." *Id.* at 01019818. And the conclusion of the Appendix—in sharp

3. Bard Failed to Preserve Any Privilege.

Privileged information generally loses work product protection when it becomes public. *See Bickley*, 266 F.R.D. at 384. While Plaintiffs agree that involuntary disclosure of work product does not always void the privilege, *see id.*, the Report became a public document during the *Phillips* trial, and Bard failed to timely request that Report (and other trial exhibits) be sealed. This "substantially increase[d] the opportunity for potential adversaries to obtain the information," destroying the privilege. *See id.*

D. Plaintiffs Have a Substantial Need For the Report

Unlike the attorney-client privilege, the work product privilege can be overcome if a plaintiff shows substantial need for the document. *See* Fed. R. Civ. P. 26(b)(3); *In re Grand Jury Subpoena*, 357 F.3d at 906. Here, Plaintiffs have a substantial need to use the Lehmann Report in discovery at trial and any purported privilege should be pierced.

First, Bard repeatedly touted Dr. Lehmann as an independent consultant who performed an investigative task for Bard as part of its regulatory compliance responsibilities. The significance of that fact and his actual conclusions are irreplaceable when deposing treating physicians upon whose shoulders Bard has historically placed the blame for the Recovery Filter failures (such as poor placement and positioning). Treating physicians should be entitled to know, when deposed, what Bard knew at the time in the manner that Bard learned it—from an independent medical consultant. If Plaintiffs are left merely with the data that Dr. Lehmann analyzed (the public MAUDE data) before coming to the conclusion that there were two safety signals and that Bard's products were failing at higher rates than its competitors, Plaintiffs will be in the awkward and unfair

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contrast to the conclusions in the main body of the Report—were that a risk-benefit analysis of the Recovery Filter could not show "an actual increased risk" of harms "when compared to competitive products." As noted above, Bard proceeded to use the explanations and excuses in the Report in its HHEs and RAPs to try to quell concerns about the Recovery Filter. The Report thus provided the statistical and analytical foundation of all of Bard's public and legal defenses to criticism of the Recovery filter, public and legal defenses that the Report itself calls into question. A document more closely tied to Bard's criminal and fraudulent scheme is difficult to envision.

position of merely arguing these conclusions, rather than presenting them as facts that Bard knew as of late 2004.

Moreover, the fact that Bard's own expert medical consultant knew for many months before he drafted his Report and summarized his findings in that Report that the devices were failing at alarming rates, is irreplaceable, particularly when Bard has historically defended these cases by blaming physicians and arguing that its product performs favorably compared to its competitors. It is also necessary to demonstrate that what Bard was reporting to the FDA and physicians was materially different than what its internal communications and medical studies were telling it.

There simply is no substantial equivalent to the Report. Yes Plaintiffs can analyze the same data Dr. Lehmann did. Plaintiffs in other cases have even hired experts to do the same work. But Plaintiffs should not be required to present the evidence in this cumbersome fashion and incur the expense and delay associated with hiring an independent expert simply to show what Bard knew as of December 2004 and communicated to several high-ranking officials in its corporation. The Report does all of that. Why waste days of trial (in every MDL case remanded for trial) with the concomitant strain on judicial and party resources to employ, prepare, present, and depose experts, along with the inevitable *Daubert* hearing exercise, when all that same information is in one report provided to several Bard employees primarily used to comply with Bard's reporting requirements to the FDA?

Plaintiffs also have a substantial need for this Report, not only for the unmatched efficacy of presenting the issue at trial, but also to avoid the prejudice that would damage Plaintiffs' case if Bard is able to affirmatively use the contents of Dr. Lehmann's Report in connection with its HHE and RAPs *without* allowing Plaintiffs to demonstrate to witnesses and the jury that the predicate document upon which those reports rely does not contain the information it is reported to contain. *See* Section III(C)(1).

E. Any Doubt About the Public and Non-Privileged Nature of the Report Should Be Resolved By Further Discovery and Evidentiary Hearing

As described above, the Report is a business document, not something designed to assist Bard's counsel in preparation for anticipated litigation. However, to the extent the Court has any doubts about the public and non-privileged nature of the Report, the Court should schedule a brief evidentiary hearing during which the parties can further develop this issue. Specifically, Plaintiffs would request that, after a reasonable opportunity to conduct discovery on the subjects, the parties present the following evidence or types of evidence at the hearing:

- All of Dr. Lehmann's time records for work relating to the Recovery device.
- Dr. Lehmann's Consulting Agreement with Bard prior to the November 2004 agreement with Bard's law department.
- Production of *all* prior drafts of Dr. Lehmann's "final" Report, including their metadata.
- The timing and actions of the DIT in gathering the MAUDE data for Dr. Lehman's review and analysis.

Plaintiffs expect this evidence to further demonstrate that Bard commissioned the Report to assist the company with its duties and responsibilities in the ordinary course of business and did so well before November. *See, e.g.*, Ex. 13, at BVPE-01-01019777-78 ("as part of an ongoing evaluation, Bard requested an independent study of the risks and benefits of the RNF, with an emphasis on its use in bariatric surgery and trauma patients. *A consultant was retained for this purpose.*") (quoting Report) (emphasis added).

F. The Court's ruling should only apply to those cases in this litigation using the Ninth Circuit's "Because Of" test

Plaintiffs generally agree that the Court's ruling on this issue should be prospective only and that prior Court's rulings on this issue unless circumstances inviting amendment or reconsideration of the issue under the forum Court's decisional applicable case law warrant further discussion. Plaintiffs do not anticipate seeking reconsideration of any of the prior Court's rulings on this issue based upon the Court's decision in this issue alone.

To the extent that other circumstances warrant relief from any existing orders precluding use of Dr. Lehmann's Report during discovery, nothing in the Court's ruling should likewise preclude Plaintiffs (or Bard) from seeking such relief, e.g., where prior courts did not have the benefit of newly-developed evidence (such as Exhibit 4 demonstrating Dr. Lehmann's history with Bard and the use of his information).

V. CONCLUSION

Because the goal of discovery in trial is to help the jury find the truth, evidentiary privileges are narrow exceptions to the general rule that parties are entitled to relevant information that bears directly on the issues, such as the Report. The work product privilege has the salutary effect of allowing lawyers to prepare their case for trial with full candor. But in order to enjoy the benefit of the work product privilege, a document or communication must be created because of a threat of litigation. Unlike Brylcreem, "a little dab will [not] do ya," and merely changing the source of Dr. Lehmann's contract and slapping a label on his Report does not make it work product. The Report was the culmination of Dr. Lehmann's work as medical director and consultant analyzing the issues to assist Bard in connection with its regulatory compliance work and its public relations crisis communication messaging. It contains no strategies, legal analysis or attorney mental impressions, and any incidental use by Bard's law department does not transform the Report into attorney work product.

And even if the document somehow was now considered work product by Bard's belated efforts to shroud it with a contract from the law department, any such privilege should be pierced because Bard waived the privilege and Plaintiffs have substantial need for use of the document.

Bard's Motion should be denied.

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RESPECTFULLY SUBMITTED this 18th day of December 2015.

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of December, 2015, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Nancy Jo Koenes

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